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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,366	05/10/2002	Mie Takahashi	967-026	1103

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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,366	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,23-27 and 31-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,23-27 and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 17 August 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11, 23-27, and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In claim 1 (line 15) and claim 23 (line 16), the terms "developed" and "chromatographically developed", respectively, are vague and indefinite. The specification does not define the terms and it is unclear how the terms limit the instant claims. Are the terms directed towards determining the presence of materials, movement of materials, or a different limitation?

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-4, 7-11, 23-25, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Killeen et al (US 5,166,051) in view of Durst et al (US 6,358,752 B1).

In the instant claims, Killeen et al teach a diagnostic test strip (i.e. biosensor) for chemical or immunological assay of whole blood analytes that comprises a substrate, a

porous detection zone membrane affixed to the substrate (i.e. porous material), and an overlay membrane affixed to the substrate and in overlying and continuous contact with the detection zone membrane, wherein the detection zone membrane contains an activated colorimetric indicator for determining a select analyte constituent in the whole blood (i.e. reagent hold part holds a reagent for marking an analyte). See column 2, lines 54-67. In addition, Killeen et al teach that the overlay membrane (i.e. carrier; specimen addition part) comprises a porous membrane of varying thickness containing a crenating agent (i.e. cell shrinking reagent) which functions to deplete the volume of fluid within the red blood cell, wherein once the cell becomes crenated or has been shrunk, it is much less malleable and flexible and becomes rigid, and in turn, less able to penetrate into the pores of the detection zone membrane (i.e. cell components are separated). See column 5, lines 5-14 and 36-41. Furthermore, Killeen et al teach the step of analyzing a signal generated from the detection zone membrane to determine the presence of any analyte, wherein the analyte is allowed to enter the detection zone once it is released from the solution of red blood cells (i.e. chromatographically developed). See column 5, lines 41-47 and column 8, lines 51-58. Although Killeen et al does not explicitly teach that the shrunk cell components are "chromatographically developed", the reference does not teach that crenated cells are immobilized immediately after being shrunk. Since Killen et al teach that the overlay membrane consists of a certain thickness (See column 9, lines 39-47 and Figure 4) and that crenated cells are trapped only at the surface of the detection zone membrane (see column 5, lines 41-44), the reference anticipates the situation wherein crenated cells

flow through the overlay membrane prior to being stopped at the interface between the overlay membrane and the detection zone membrane. Therefore, since travel of crenated cells is included in the teachings of Killeen et al, the reference teaches the limitation of shrunk cell components that are "chromatographically developed".

However, Killeen et al fail to teach a reaction layer on which a reaction between the analyte in the liquid specimen and a marker reagent eluted from the marker reagent holding part is carried out.

Durst et al reference teaches a test strip with a capture portion 110 (i.e. reaction layer) downstream of layers 104 and 106, in order to provide immobilized probes that isolate analytes of interest allow other materials to flow past the capture portion. See column 11, line 39 to column 12, line 23; and Figures 1 and 6.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Killeen et al with a test strip with a capture portion 110 (i.e. reaction layer) downstream of layers 104 and 106, as taught by Durst et al, in order to provide immobilized probes that isolate analytes of interest allow other materials to flow past the capture portion. The immobilized probes in the detection area bind only to analytes of interest and not to other materials, thereby providing a more accurate detection means in the reaction area, and providing motivation to combine the capture portion with the device of Killeen et al. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the capture portion of Durst et al in the device of Killeen et al, since both Killeen et al and Durst et al teach test strips with flow in one direction.

With regards to claim 3, Killeen et al teach that analytes include bacteria. See column 6, lines 17-18.

With regards to claims 4 and 25, Killeen et al teach that preferred crenating agents are inorganic salts. See column 5, lines 48-56.

With regards to claims 7-9, 11, and 33, Killeen et al teach that the test strips are dry. See column 8, lines 40-44. With regards to claims 7-9, the limitations "dried naturally or dried by air-drying", "dried by freeze-drying", and "dried by heat drying" are product-by-process claims and therefore not given patentable weight. Accordingly, only the structural limitation of a carrier that carries the cell shrinkage reagent, wherein the carrier is dry, has been considered.

With regards to claims 10 and 32, Killeen et al teach that the test strip contains a labeled reagent zone, a second trapping zone, and a third detection zone for label detection (i.e. one-step immunochromatographic test strip). See column 8, line 59 to column 9, line 24.

With regards to claims 31 and 34, Killeen et al teaches that overlay membranes were impregnated with one molar NaCl solution (i.e. concentration of cell shrinkage reagent is 0.1 ~ 5.0 M or 0.5 ~ 5.0 M). See column 11, lines 18-20 and column 12, lines 4-5.

9. Claims 5-6 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Killeen et al (US 5,166,051) in view of Durst et al (US 6,358,752 B1) as applied to claim 1 above, and further in view of Fruitstone et al (US 4,259,207).

Killeen et al and Durst et al references have been disclosed above, but fail to teach that the cell shrinkage reagent is amino acid or saccharide.

Fruitstone et al teach that solutes such as amino acids and sugars may be employed to control osmolality, in order for cells to become crenated if the osmolality of the solution is too high. See column 3, lines 3-20.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Killeen et al and Durst et al, with solutes such as amino acids and sugars that may be employed to control osmolality, as taught by Fruitstone et al, in order for cells to become crenated if the osmolality of the solution is too high. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including amino acid or sugar, as taught by Fruitstone et al, in the method of Killeen et al and Durst et al, since Killeen et al and Durst et al teach that the crenating agent may be any constituent or composition which effectively reduce the volume of water in blood cells (see column 5, lines 48-51), and amino acids and sugars are examples of constituents that reduce the volume of water in blood cells.

Response to Arguments

10. On pages 8-9 of the Remarks, filed 17 August 2005, Applicants traversed the rejection of claims 1-4, 7-14, 21-25, and 31-34 under 35 U.S.C. 102(b) as being

anticipated by Killeen et al. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

11. Although Applicant's arguments have been considered moot, Applicants present an argument in the Remarks with regards to Killeen et al reference that needs to be addressed. Applicants argue that Killeen et al differs from the claimed invention because Killeen et al teach a membrane that prevents red blood cells from moving to the detection zone, whereas the claimed invention requires that "shrunk cell components are developed together with the liquid specimen chromatographically downstream along the biosensor" (see page 8, 3rd paragraph). Applicants have amended independent claims 1 and 23 to include the above situation, which Applicants contend is sufficient to overcome the teaching of Killeen et al.

Applicant's arguments have been fully considered but they are not persuasive. The term "chromatographically developed", as stated in the previous Office Action, is vague and indefinite. The specification does not provide a definition for the term, and it is unclear what is meant by something being "developed". Lacking a definition for the term "chromatographically developed", the previous Office Action interpreted to indicate the term as applying to means or steps for moving fluid or reagents downstream in a test strip (see pages 6-7 of the previous Office Action). Although Applicants amended claims 1 and 23 with the term "chromatographically developed", the current claims do not recite anything other than the situation wherein the shrunk cell components and liquid specimen are *intended* to travel all the way downstream together. The amended

limitation "wherein the cell components in the liquid specimen are shrunk by the cell shrinkage reagent, and the shrunk cell components are developed together with the liquid specimen toward said reaction layer that is provided chromatographically downstream" only claims movement of shrunk cells and liquid specimen ***toward*** the reaction layer, and does not actually claim that the shrunk cells and liquid specimen reach the reaction layer together. As stated in response to arguments section in the previous Office Action, the overlay membrane of Killeen et al contains a vertical dimension and the crenated cells are stopped only at the connection between the overlay membrane and the detection membrane. Therefore, the crenated cells do travel downstream with the liquid sample for part of the biosensor. Since it is interpreted that the term "chromatographically developed" only indicates that materials travel downstream in a test strip, Killeen et al satisfies this requirement by teaching crenated cells that travel downstream in a test strip for part of the strip towards a reaction layer.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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